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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,670	01/05/2006	Thomas Gore	I-2002.025 US	4798

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INTERVET INC.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,670	GORE ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/20/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2007 has been entered.

Response to Amendment

The amendments to the claims filed June 20, 2007 has been entered. Claims 1-27 have been cancelled. New claims 28-42 have been added.

Status of the Claims

Claims 28-42 are pending and under examination.

Response to Arguments

Applicant's arguments filed June 20, 2007 have been fully considered and will be addressed as they pertain to the newly added claims and new rejections.

Claim Rejections - 35 USC § 112

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot because claim 6 has been cancelled.

Claim Rejections - 35 USC § 103

The rejection of claims 1-7, 14-15 and 23-27 under 35 U.S.C. 103(a) as being unpatentable over Poulet et al., Mochizuki et al., Miller et al., Schwartz et al. and Pratelli et al. is moot because the claims have been cancelled.

The rejection of claims 8-13 and 17-22 under 35 U.S.C. 103(a) as being unpatentable over the combination of Poulet et al., Mochizuki et al., Schwartz et al. and Pratelli et al. as applied to claims 1-7, 14-15 and 23-27 above, and further in view of Wilhem et al. is moot because the claims have been cancelled.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. (US Patent No. 4,193,990, Mar. 1980) (Appel '0) and Appel et al. (US Patent No. 4,193,991, Mar. 1980) (Appel '1) in view of Pratelli et al. (Journal of Veterinary Diagnostic Investigation, 1999, Vol. 11, pages 365-367).

The claimed invention is drawn to a vaccine comprising a Minute virus of canine (MCV, also known as Canine Parvovirus-1 (CPV-1)) antigen, wherein the antigen is an inactivated MCV, wherein the antigen is an attenuated live MCV.

Appel '0 teaches a vaccine against canine parvovirus (CPV) using a modified live (attenuated) or inactivated virus vaccine (Abstract). Appel '1 teaches methods of protecting dogs against canine parvoviruses and a method of producing an inactivated canine parvovirus vaccine from a virulent strain of CPV (Abstract). Neither Appel '0 nor Appel '1 teach a vaccine comprising MCV (CPV-1).

Pratelli et al. (hereinafter Pratelli) teaches that CPV-1, also known as MCV, causes severe hemorrhagic gastroenteritis in dogs and pneumonitis and enteritis in neonatal pups and fetal deaths in pregnant bitches (page 365). Pratelli also discloses that antibodies to CPV-1 are common in the dog population in the U.S. and elsewhere (p. 367).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to make a vaccine for MCV. The person of ordinary skill in the art would have been motivated to make a vaccine for MCV because Pratelli teaches the importance of the canine pathogen, and reasonably would have expected success because Appel made a vaccine from a virulent strain of CPV. Furthermore, the widespread presence of antibodies to CPV-1 in the canine population indicates that dogs are able to mount an effective immune response to CPV-1.

Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. 4,193,990 and Appel et al. 4,193,991 in view of Pratelli et al. as applied to claims 28, 30 and 32 above, and further in view of Audonnet et al. (US Patent No. 6,159,477, Dec. 2000).

The claimed invention is drawn to the invention described above wherein the vaccine comprises at least one additional antigen of canine herpesvirus (CHV), canine rotavirus (CRV) or canine parvovirus type 2 (CPV-2), wherein the MCV antigen is inactivated, wherein the MCV antigen is attenuated.

Appel teaches a vaccine against CPV. Pratelli teaches that MCV, a.k.a. CPV-1 is an important canine pathogen. Neither Appel '0, Appel '1, nor Pratelli teach adding at least one more canine pathogen antigen to the vaccine.

Audonnet et al. (hereinafter Audonnet) teaches a recombinant live vaccine encoding antigens from different canine pathogens (Abstract and column 1, lines 24-28). Audonnet also teaches vaccinating dogs at the same time against different canine pathogens (column 1, lines 53-55).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to prepare a multivalent vaccine for canine pathogens. The person of ordinary skill in the art would have been motivated to add antigens from different pathogens because multivalent vaccine for dogs are well known in the art and Audonnet teaches vaccinating dogs against different canine pathogens in one vaccine.

Claims 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. 4,193,990 and Appel et al. 4,193,991 in view of Pratelli et al. and Audonnet et al. as applied to claims 28-33 above, and further in view of Poulet et al. (Veterinary Record, 2001, Vol. 148, No. 22, pages 691-695) and Correa (Alabama Cooperative Extension System, November 2002, 7 pages).

The claimed invention is drawn to the invention described above and a method of protecting puppies against MCV, a.k.a. CPV-1 comprising administering a vaccine comprising MCV antigen to a pregnant bitch and administering colostrums to puppy or puppies within 48 hours of whelp, wherein colostrums is administer within 24 hours of whelp, wherein maternal antibodies are transferred by allowing the puppy to nurse within 24 hours.

Appel teaches a vaccine against CPV. Pratelli teaches that MCV, a.k.a. CPV-1 is an important canine pathogen. Audonnet teaches a multivalent vaccine with antigens of different canine pathogens. Neither Appel '0, Appel '1, Pratelli nor Audonnet teach administering the vaccine to pregnant bitches or administering colostrums to puppies within 24 or 48 hours.

Poulet et al. (hereinafter Poulet) teaches a method of vaccinating pregnant bitches against CHV-1 wherein the puppies were protected after nursing (Abstract).

Correa teaches the importance of puppies consuming colostrums within the first 12 to 24 hours after birth (page 6, paragraph joining columns 1 and 2). Correa also teaches that the colostrum, mother's first milk, contains antibodies, which provide protection from infectious diseases (page 6, paragraph joining columns 1 and 2).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to vaccinate the bitch and allow the puppies to nurse within 24 hours. The person of ordinary skill in the art would have been motivated to vaccinate the pregnant bitch because Poulet teaches the importance for survival of the puppies. The person of ordinary skill in the art would have also been motivated to allow the puppies to nurse in the first 24 hours because Correa teaches the importance of puppies receiving colostrums to absorb antibodies to protect from diseases.

The combination of references teaches the limitations of the instant claimed invention.

Applicant argues that none of references teach or suggest a vaccine comprising an MCV antigen. Applicant also states that the Examiner has not provided any evidence in support of the presumption that an MCV vaccine could be made from an MCV viral isolate. Applicant further states that CPV-1 (a.k.a. MCV) is genetically different from CPV-2. These arguments are not persuasive. The prior art shows that dogs commonly possess antibodies to CPV-1. The fact that severe pathology appears to occur mostly in pups (with undeveloped immune systems) further suggested that adults are able to mount an effective immune response to the virus. Therefore it would have been prima facie obvious to immunize pregnant bitches in order to provide a high level of anti-CPV-1 antibodies in colostrum to protect vulnerable pups. It would have been obvious to use attenuated or inactivated virus because it was known that the virus itself can induce a protective immune response in adult dogs.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Larson et al. (AJVR, April 1997, Vol. 58, No. 4, pages 360-363) teaches about multicomponent canine vaccines with CPV and their ability to stimulate antibody production and protective immunity.

Wood et al. (US Patent No. 4,971,793, Nov. 1990) teaches about recombinant subunit vaccine for protecting dogs against CPV. Wood et al. also teaches about inactivated vaccines compared to modified live vaccines in levels of immunity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

July 12, 2007

/Bruce Campell/
Bruce Campell
Supervisory Patent Examiner
Art Unit 1648